

tional apparatus and methods is that touching the catheter to any surface outside of the sterile field, as when lubricating jelly is applied, for instance, increases the risk of contamination and urinary tract infection. In contrast, with the present kit, if the sheathed catheter touches anything outside the sterile field, the insertable portion of the catheter remains sterile. Another potential problem associated with conventional catheterization kits and procedures is that, if a glove touches anything outside the sterile field and then touches the catheter, the catheter becomes contaminated. If a sheathed catheter assembly is employed instead, and if a glove becomes contaminated, the catheter nevertheless remains sterile inside the protective sheath. Thus, the risk of infection and patient morbidity is reduced or eliminated with use of the new catheterization kit and catheterization procedure.

[0044] The above-mentioned items omitted from conventional cath trays are not needed for carrying out a streamlined catheterization procedure with the above-described sheathed catheter assembly and maintaining sterile technique.

Catheterization Procedure

[0045] The simplified catheterization kit is preferably employed as follows: After opening the sanitary wrapper **82**, the nurse dons the gloves **80** and places the fenestrated drape, if provided, around the patient's genitalia. The packet **79** containing the antiseptic swabs is opened and the urethral area around the urethral opening is cleansed using the antiseptic swabs. Referring to FIG. 1A, the nurse grasps catheter **10** through the soft, flexible sheath **40a** near the tip end of the catheter and advances the catheter tip into the patient's urethra. If necessary, the sheath terminus **44a** is first opened to allow the catheter tip to emerge. The sheath **40a** is pulled back to expose the catheter tip, giving the catheter assembly an appearance similar to that shown in FIG. 1B. As the catheter tip is advanced by the nurse, a portion of sheath **40a** becomes gathered or collapses toward sheath attachment point **12a**. By appropriately repositioning the nurse's grasp on catheter **10** through sheath **40a**, and continuing to gently urge the catheter into the urethra and toward the bladder, the sheath **40a** is caused to continue gathering toward sheath attachment point **12a**. When the catheter tip enters the patient's bladder a sufficient distance to commence draining of accumulated urine, and advanced into the bladder sufficiently (e.g., about 1 cm) to establish optimal urine flow, further insertion ceases. As a result, the position on catheter **10** that is at the urethral opening when insertion ceases is termed the "insertion stop location" **26a**.

[0046] A catheter assembly like any of those shown in FIGS. 1C, and 2-4 may be substituted for the catheter assembly shown in FIG. 1A or 1B, and are used similarly. The insertion stop location (insertion stop location **26a** in FIG. 1A) on the catheter will vary somewhat in different situations of use. The insertion stop location will also vary somewhat with alternative catheter assembly designs. For instance, in the embodiment shown in FIG. 3, the maximum insertable length of catheter, and the insertion stop location are limited by an expanded diameter or flared portion **18** of the catheter. In FIG. 2, insertion stop location **26d** of the insertable portion is in an area between the catheter tip and the sheath attachment point **12d**, but is spaced apart from the end **32** of the catheter. Prior to commencement of urine

drainage, the free end or recess **36a-e** (FIGS. 1-3), or extension **60** (FIG. 4), as applicable, is positioned on the urine receptacle, so that urine can drain into the tray without permitting the catheter to contact the collected urine. Alternatively, any other suitable urine receptacle may be used instead of the disposable tray provided as part of the kit. When employing an embodiment of the catheter assembly that has no "free end" (similar in appearance to FIG. 3, but wherein distance "d" is essentially zero), the attachment point **12e**, or closure **50e** may be positioned or rested on tray **71** for collection of urine.

[0047] After commencement of urine flow, the outlet **34** or spout **62** (FIG. 4) may be directed briefly into the specimen container **78**, to collect a sterile specimen, as needed. Upon completion of urine evacuation, catheter **10** or **73** is simply withdrawn from the urethra and disposed of along with the other components of the kit. If desired, the catheter may be retracted into the sheath prior to disposal. The entire catheterization process can usually be accomplished by a nurse in about 5-7 minutes, maintaining sterile technique throughout the procedure.

[0048] Because multiple steps are involved in a typical inpatient catheterization, a nurse necessarily spends a significant amount of time (e.g., 10-15 minutes) performing each catheterization. The conventional catheterization kit and sterile procedure that is used in virtually every inpatient hospital around the world has remained essentially the same for 50 years. The new kit and simplified procedure offers a way to simplify and streamline inpatient catheterization procedures without compromising sterile technique. Every item that the new kit eliminates from the customary catheterization setup will decrease the number of procedural steps, and also reduces the amount of nursing time needed. Fewer steps also reduces the patient's risk for urinary tract infection, and decreases inconvenience for the patient. It is estimated that at least 50% less nursing time is required to carry out a catheterization procedure with the new kit.

What is claimed is:

1. A urinary catheter assembly comprising:

a catheter comprising a first end, a second end having a urine outlet, a urethra-insertable portion containing an insertion stop location, and a non-insertable portion;

a pliable sheath comprising a lumen and enclosing all or part of said insertable portion, and having a terminus sealingly attached to said catheter at an attachment point disposed between said insertion stop location and said second end, wherein the distance along said catheter from said attachment point to said second end is no more than about one-third of the total length of the catheter from said first end to said second end, provided that said lumen and said urine outlet are not in mutual fluid communication.

2. The catheter assembly of claim 1 further comprising an introducer attached to said sheath opposite said terminus, said introducer and said sheath together enclosing all of said urethra-insertable portion.

3. The catheter assembly of claim 1, wherein at least part of said non-insertable portion comprises an uncovered region of said catheter outside said sheath.